REMARKS

Applicants thank the Examiner for the withdrawal of the 35 U.S.C. § 101 and the 35 U.S.C. § 102(b) rejections of Claims 3 and 7 and Claims 9-10 respectively.

Entry of the forgoing and further and favorable consideration of the subject application are respectfully requested. As stated correctly in the Final Office Action, Claims 1-13 are pending. The Examiner has finally rejected Claims 1-13.

By the present amendment, Claims 1, 5 and 9 have been amended to remove the vague language "selected from the group consisting", as such claims only recite the previously elected nucleotide or polypeptide sequence. No prohibited new matter has been introduced by way of the above amendments. Claims 11-13 have been cancelled. Applicants reserve the right to file a division or continuation on the cancelled subject matter.

35 U.S.C. § 112, first paragraph Rejection – Written Description

The Examiner has rejected Claims 1-13 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement. Applicants respectfully traverse. Applicants note that Claims 11-13 have been cancelled by the foregoing amendments, thus rendering any rejection of the cancelled claims moot. Specifically, the Examiner alleges that "without providing description of both a start and stop codon, Applicants have only provided support for the specifically identified fragment" encoded by SEQ ID NO:20623, and that accordingly one of skill in the art would conclude that the disclosure fails to provide a representative number of species to describe the genus. For the reasons set forth herein, Applicants respectfully disagree and assert that pending Claims 1-10 are fully supported in the Specification in accordance with the written description requirement of 35 U.S.C. §112, first paragraph.

The guidelines for examination of patent applications under 35 U.S.C. § 112, first paragraph, "written description", as shown in the Federal Register Vol. 66, No. 4, at page 1100, state:

> The Guidelines have been revised to clarify that an applicant must provide a description of the claimed invention which shows that applicant was in possession of the claimed invention. The suggestion to emphasize that the written description requirement must put the public in possession of the invention has not been adopted...The written description requirement, a question of fact, ensures that the inventor conveys to others that he or she had possession of the claimed invention...

The Federal Register, Vol. 66, No. 4, at page 1103 also states:

> The written description requirement does not require the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow *persons of ordinary skill in the art* to recognize that [he or she] invented what is claimed.' Thus § 112, ¶ 1, ensures that, as of the filing date, the inventor conveyed with reasonable clarity to *those of skill in the art* that he was in possession of the subject matter of the claims. (emphasis in original).

The standard for the written description requirement is also described in M.P.E.P. § 2136. In relevant part, the test is described as follows:

> An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including . . . the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 U.S.P.Q.2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 U.S.P.Q.2d 1016, 1021 (Fed. Cir. 1991)(one must define a compound by "whatever characteristics sufficiently distinguish it"). M.P.E.P. § 2163(I).

A disclosure "is sufficient if the disclosure teaches those skilled in the art what the invention is and how to practice it." *In re Grimme, Keil and Schmitz,* 124 U.S.P.Q. 449, 502 (C.C.P.A. 1960). Furthermore, "there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure." *Falkner v. Inglis*, 79 U.S.P.Q.2d 1001 (Fed. Cir. 2006). "Indeed, a requirement that patentees recite known DNA structures, if one existed, would serve no goal of the written description requirement. It would neither enforce the quid pro quo between the patentee and the public by forcing the disclosure of new information, nor would it be necessary to demonstrate to a person of ordinary skill in the art that the patentee was in possession of the claimed invention." *Id.*

The Examiner must set forth express findings of fact which support an alleged lack of written description conclusion. These findings should (a) identify the claim limitation at issue and (b) establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed. M.P.E.P. § 2163.05 (Statement of Rejection Requirements)

Claims 1-13 have been rejected for allegedly failing to provide description of both a start and stop codon, and that Applicants have only provided support for the specifically identified fragment encoded by SEQ ID NO:20623. Applicants respectfully disagree. The Specification provides that the *A. fumigatus* sequences were analyzed for the presence of open reading frames comprising at least 180 nucleotides, for example at page 28, lines 23-24. The Specification, for example at page 33, line 25 through page 34, line 9, further states that Table 2 provides a list of open reading frames, a region of nucleic acids which encodes polypeptides, which was determined from stop to stop codons. Applicants assert that further analysis was performed to further identify open reading frames. For example, the Specification, at page 34, lines 1-3, teaches that the particular functions of the polypeptides encoded by each open reading frame were then predicted based on homology matches with known proteins encoded by open reading frames in other organisms.

The Specification teaches, at page 34, lines 11-13 that, "It will be recognized by one skilled in the art that the natural translation initiation sites will correspond to ATG, GTG or TTG." Furthermore, the Specification, at page 34, lines 19-20, also teaches that "[t]he correct start codons can be generally identified without undue experimentation because only a few codons need be tested". Additionally, Applicants have provided the Sequence Listing for the nucleic acid and amino acid sequences. Specifically, the Sequence Listing provides that the nucleic acid sequence encoding SEQ ID NO:20623 is as follows:

agtttccatc	taacagccta	cagcttcaag	gacgatgttc	tcgatgtcat	**catg**tcgcaa	60
cgtgaaaagc	ggaatgaggc	**tatggcgatg**	gctgcggagg	ccgat**atg**ga	tgcggctgcg	120
gctccctcg**a**	**tg**tttcctcc	cgag**ttg**act	cgtcgataca	cactcaattt	caagcctctt	180
actccgtctg	ggtcgagcag	cgaccggtac	tccaaggctc	tcgcagtccg	taat**gtg**cga	240
gcagagcacc	tgggtagtct	gatcacggtt	cgcggtatta	caactcgtgt	ctcggacgtc	300
aaaccatcag	tccagatcaa	cgcctatact	tgcgatcggt	gtggatgcga	a**gtgt**ttcag	360
ccagttacca	caaaacaatt	tctgcct**atg**	actgagtgc**t**	**tg**tctgaaga	gtgcaagcag	420
aacaactcga	agggacaatt	gtttctttcc	actcgtgcct	cgaaatttgt	tcccttccag	480
gaggtcaaga	tccaagaaat	ggcagatcag	gttcctgttg	gtcacattcc	acgaacacta	540
accattcact	gccatgggag	tctgacacga	caactcaacc	ctggagatgt	tgtcgacgtc	600
gcgggcatct	tccttcccac	accttacacc	gggttcaggg	ccatccgtgc	cggcctc**ttg**	660
accgacacat	ac**ttg**gaagc	tcagcatatc	acacatcaca	agaagtcgta	caatgatctg	720
acg**atg**gaca	gccagacgct	ccgaaagatt	gaacagtacc	aaaagtctgg	aaat**atg**tac	780
gagtacctgt	ctcgttccat	cgctcccgag	atttacggcc	atcttgacgt	gaagaaagcc	840
ttgcttcttc	tacttattgg	aggtgtgaca	aaggaa**atgg**	gcgacggcat	gcatatccgt	900
ggtgacatca	atatctgcct	g**atg**ggtgat	cctggtgtcg	ccaaatcgca	**attg**ctgaaa	960
tatattgcca	aggttgctcc	acgaggc**gtg**	tacactactg	gacgaggtag	cagtggagtt	1020
ggtcttaccg	ctgctgttat	gagagaccct	gtaacggatg	ag**atggtg**ct	ggagggagga	1080
gccctggttt	tggcggacaa	tggcatttgc	tgtatcgatg	agttcgacaa	g**atg**gacgat	1140
gccgatcgga	ctgctatcca	tgaa**gtgatg**	gagcaacaga	ccatctccat	ttccaaggct	1200
ggcatcacaa	caaccctgaa	cgccgtaact	tccatttctg	gctgcagcca	ttctttttt	1260
atggacggaa	caacccgcga	attttttcca	**gtg**gagaaca	tcaccttccc	cgccgca**ttg**	1320
ctctcgcgtt	tcgacgtcat	gttcttcatc	ntagacactc	cacagcggga	agccgatgag	1380
gaattagcca	accacgtcgc	gtacgtccac	**atg**cacaaca	aacaccccga	ggtcgacgat	1440
gccggagtct	tgttcacacc	aaatgaagtc	cgtcagtaca	tcgctaaggc	gcgcacatat	1500
cggcctgtcg	tgccttcgtc	agtttccgat	tac**atg**gtcg	gagcttacgt	gcga**atg**agg	1560
aagcaacaaa	agagcgacga	agccagcaag	aagcaattct	ctcat**gtg**ac	tccccgtact	1620
ttacttggtg	tcgttcgtct	ctcgcaagct	cttgcccgtc	ttcgcttcag	cgaagaggtc	1680
atcagggagg	atgtcgatga	ggc**ttt**gcgt	cttatcgagg	tcagcaaagc	atcactggcc	1740
aatgacggtc	attccggcat	agaccagagc	cccagtagca	agatctacaa	tctcattcgc	1800
ggt**atg**cgcg	agagcggtgc	tgccgctgtt	ggggacggtg	aagagggtga	acttagc**atg**	1860
agaaggatta	gggaacgcgt	tcttgccaaa	ggcttcacag	aggatcagct	caca**atg**gcg	1920
atcgacgaat	acgaagagct	taatgtacgt	gttgtcagct	tgaatagtcc	ttggtggctc	1980
ttacta**atgt**	ct**ttg**ttcct	ttgcaggttt	ggcaagtcgt	taacaacgga	actcgcctca	2040
ttttcttgga	tctcggaggc	g**atg**aggcaa	tggacatata	ataggccagc	aaacggttgc	2100

agtttagact ggcaaaaagt aatcactgta gtctgctga 2139

Additionally, the Sequence Listing provides that the amino acid sequence of the polypeptide encoded by SEQ ID NO:42779 is as follows:

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Ser Phe His Leu Thr Ala Tyr Ser Phe Lys Asp Asp Val Leu Asp Val
1               5                  10                  15
Ile Met Ser Gln Arg Glu Lys Arg Asn Glu Ala Met Ala Met Ala Ala
            20                  25                  30
Glu Ala Asp Met Asp Ala Ala Ala Ala Pro Ser Met Phe Pro Pro Glu
        35                  40                  45
Leu Thr Arg Arg Tyr Thr Leu Asn Phe Lys Pro Leu Thr Pro Ser Gly
    50                  55                  60
Ser Ser Ser Asp Arg Tyr Ser Lys Ala Leu Ala Val Arg Asn Val Arg
65                  70                  75                  80
Ala Glu His Leu Gly Ser Leu Ile Thr Val Arg Gly Ile Thr Thr Arg
                85                  90                  95
Val Ser Asp Val Lys Pro Ser Val Gln Ile Asn Ala Tyr Thr Cys Asp
            100                 105                 110
Arg Cys Gly Cys Glu Val Phe Gln Pro Val Thr Thr Lys Gln Phe Leu
        115                 120                 125
Pro Met Thr Glu Cys Leu Ser Glu Glu Cys Lys Gln Asn Asn Ser Lys
    130                 135                 140
Gly Gln Leu Phe Leu Ser Thr Arg Ala Ser Lys Phe Val Pro Phe Gln
145                 150                 155                 160
Glu Val Lys Ile Gln Glu Met Ala Asp Gln Val Pro Val Gly His Ile
                165                 170                 175
Pro Arg Thr Leu Thr Ile His Cys His Gly Ser Leu Thr Arg Gln Leu
            180                 185                 190
Asn Pro Gly Asp Val Val Asp Val Ala Gly Ile Phe Leu Pro Thr Pro
        195                 200                 205
Tyr Thr Gly Phe Arg Ala Ile Arg Ala Gly Leu Leu Thr Asp Thr Tyr
    210                 215                 220
Leu Glu Ala Gln His Ile Thr His His Lys Lys Ser Tyr Asn Asp Leu
225                 230                 235                 240
Thr Met Asp Ser Gln Thr Leu Arg Lys Ile Glu Gln Tyr Gln Lys Ser
                245                 250                 255
Gly Asn Met Tyr Glu Tyr Leu Ser Arg Ser Ile Ala Pro Glu Ile Tyr
            260                 265                 270
Gly His Leu Asp Val Lys Lys Ala Leu Leu Leu Leu Leu Ile Gly Gly
        275                 280                 285
Val Thr Lys Glu Met Gly Asp Gly Met His Ile Arg Gly Asp Ile Asn
    290                 295                 300
Ile Cys Leu Met Gly Asp Pro Gly Val Ala Lys Ser Gln Leu Leu Lys
305                 310                 315                 320
Tyr Ile Ala Lys Val Ala Pro Arg Gly Val Tyr Thr Thr Gly Arg Gly
                325                 330                 335
Ser Ser Gly Val Gly Leu Thr Ala Ala Val Met Arg Asp Pro Val Thr
            340                 345                 350
Asp Glu Met Val Leu Glu Gly Gly Ala Leu Val Leu Ala Asp Asn Gly
        355                 360                 365
Ile Cys Cys Ile Asp Glu Phe Asp Lys Met Asp Asp Ala Asp Arg Thr
    370                 375                 380
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Ala Ile His Glu **Val** **Met** Glu Gln Gln Thr Ile Ser Ile Ser Lys Ala
385 390 395 400
Gly Ile Thr Thr Thr Leu Asn Ala Val Thr Ser Ile Ser Gly Cys Ser
405 410 415
His Ser Phe Phe **Met** Asp Gly Thr Thr Arg Glu Phe Phe Pro **Val** Glu
420 425 430
Asn Ile Thr Phe Pro Ala Ala **Leu** Leu Ser Arg Phe Asp Val Met Phe
435 440 445
Phe Ile Xaa Asp Thr Pro Gln Arg Glu Ala Asp Glu Glu Leu Ala Asn
450 455 460
His Val Ala Tyr Val His **Met** His Asn Lys His Pro Glu Val Asp Asp
465 470 475 480
Ala Gly Val Leu Phe Thr Pro Asn Glu Val Arg Gln Tyr Ile Ala Lys
485 490 495
Ala Arg Thr Tyr Arg Pro Val Val Pro Ser Ser Val Ser Asp Tyr **Met**
500 505 510
Val Gly Ala Tyr Val Arg **Met** Arg Lys Gln Gln Lys Ser Asp Glu Ala
515 520 525
Ser Lys Lys Gln Phe Ser His **Val** Thr Pro Arg Thr Leu Leu Gly Val
530 535 540
Val Arg Leu Ser Gln Ala Leu Ala Arg Leu Arg Phe Ser Glu Glu Val
545 550 555 560
Ile Arg Glu Asp Val Asp Glu Ala **Leu** Arg Leu Ile Glu Val Ser Lys
565 570 575
Ala Ser Leu Ala Asn Asp Gly His Ser Gly Ile Asp Gln Ser Pro Ser
580 585 590
Ser Lys Ile Tyr Asn Leu Ile Arg Gly **Met** Arg Glu Ser Gly Ala Ala
595 600 605
Ala Val Gly Asp Gly Glu Glu Gly Glu Leu Ser **Met** Arg Arg Ile Arg
610 615 620
Glu Arg Val Leu Ala Lys Gly Phe Thr Glu Asp Gln Leu Thr **Met** Ala
625 630 635 640
Ile Asp Glu Tyr Glu Glu Leu Asn Val Arg Val Val Ser Leu Asn Ser
645 650 655
Pro Trp Trp Leu Leu Leu **Met** Ser **Leu** Phe Leu Cys Arg Phe Gly Lys
660 665 670
Ser Leu Thr Thr Glu Leu Ala Ser Phe Ser Trp Ile Ser Glu **Ala** Met
675 680 685
Arg Gln Trp Thr Tyr Asn Arg Pro Ala Asn Gly Cys Ser Leu Asp Trp
690 695 700
Gln Lys Val Ile Thr Val Val Cys
705 710

To illustrate that one with ordinary skill in the relevant art could easily identify the natural translation initiation site and that accordingly, Applicants had possession of the claimed invention at the time of filing, Applicants have identified the natural translation initiation sites, which correspond to ATG, GTG or TTG, present within the claimed structure of SEQ ID NO:20623 by presenting them in **bold** font. In addition, Applicants have provided the coding portion of the amino acid sequence encoded by SEQ ID NO:42779 and have presented the corresponding natural translation initiation sites in **bold** font. Applicants respectfully assert that

the structures of both the nucleic acid corresponding to SEQ ID NO:20623, and the polypeptide SEQ ID NO:42779 encoded thereby, are clearly disclosed in the Specification and in particular in the Sequence Listing. Accordingly, in the usage of the present Specification, *A. fumigatus* polypeptides encoded by sequences disclosed include polypeptides encoded within the disclosed open reading frames beginning from a start codon identifiable therein.

Despite the Examiner's allegations that Applicants have failed to adequately describe the structure of the nucleotides, such allegations do not *per se* reflect non-compliance with the written description requirement of 35 U.S.C. §112, first paragraph. By failing to provide reasons why one of ordinary skill in the art would not have recognized that Applicants were in possession of the claimed invention in view of the disclosure set forth in the application, the Examiner has failed to establish a *prima facie* case in support of his conclusion that Applicants have allegedly failed to comply with the written description requirement.

The Examiner has failed to substantiate his conclusion that the claimed sequence is a fragment of a full length protein. M.P.E.P. § 2144.03 states that the standard of review applied to findings of fact is the substantial evidence standard. Compliance with written description is a fact based inquiry. The Examiner appears to be making statements that the fact the sequence is a fragment is well known based on the assertion that codons are stop/start codons. Official notice unsupported by documentary evidence should only be taken by the Examiner where the facts are asserted to be well-known, or to be common knowledge in the art are capable of *instant and unquestionable demonstration* and being well known. (emphasis added) See *In re Ahlert* 424 F.2d 1088, 1091, 165 U.S.P.Q. 418, 420 (CCPA 1970). It is not appropriate for the Examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. Conclusory statements are insufficient. The Examiner must set forth the rationale upon which he relies in rendering his conclusions. In this case, the Examiner concludes that the claimed sequence is a fragment of a full length protein and not a complete sequence without providing a clear rationale why this would be well-known. Additionally, the technical line of reasoning underlying a decision to take such notice must be clear and unmistakable. The Examiner must

provide specific factual findings predicated on sound technical and scientific reasoning to support his or her conclusion of common knowledge. *See In re Soli*, 317 F.2d 941, 945-46, 137 U.S.P.Q. 797, 800 (CCPA 1963). Applicants respectfully assert that the Examiner has failed to provide scientific reasoning to support his conclusion that the claimed sequence is a fragment of a full length protein and not a complete sequence.

Applicants respectfully assert that the structures of both the nucleic acid corresponding to SEQ ID NO:20623 and the polypeptide SEQ ID NO:42779 encoded thereby, are clearly disclosed in the Sequence Listing. Applicants respectfully maintain that in light of the present disclosure, one of ordinary skill in the relevant art could easily identify the correct start codon in the open reading frame and that Applicants had possession of the claimed invention at the time of filing.

Claims 1-13 have also been rejected by the Examiner as the Specification allegedly fails to describe the common attributes or structural characteristics that identify members of the genus. Claims 11-13 have been cancelled by the present amendment, thus rendering any rejection of those claim moot. Specifically, the Examiner alleges that without providing both a start and stop codon for SEQ ID NO:20623 one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Applicants respectfully disagree.

As stated on page 1102 of the Federal Register, Vol. 66, No. 4, disclosure of a single species can provide an adequate written description of a generic claim, if one skilled in the art would recognize that the disclosure of the species includes the genus:

> The Guidelines now indicate that a single species may, in some instances, provide an adequate written description of a generic claim when the description of the species would evidence to one of ordinary skill in the art that the invention includes the genus.

One skilled in the art would recognize that Applicants had possession of the claimed nucleic acid and amino acid sequences. One of ordinary skill in the art would be able to "visualize or recognize the identity of the members of the genus" of Applicants' claimed subject matter (*University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997)).

The Court of Appeals for the Federal Circuit held that because the Applicant in *Fiers v. Sugano,* 25 U.S.P.Q.2d 1601, 1605 (Fed. Cir. 1993), cited by the Examiner, did not disclose any nucleic acid sequence, the application failed to satisfy the written description requirement since the application could not reasonably convey to one skilled in the art that the party had possession of the claimed subject matter. In particular, the *Fiers* court stated:

> An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. *Id. at 1606.*

Unlike the Applicant in *Fiers*, who did not disclose any nucleic acid sequence, Applicants of the instant invention have provided both the nucleic acid and the corresponding amino acid sequence information for the claimed subject matter (*Id.*). Applicants have not "merely" made a statement regarding a nucleic acid sequence. Thus, Applicants' claimed invention meets the requirements of 35 U.S.C. § 112, first paragraph, under the written description guidelines set forth in the Federal Register. As discussed *supra*, Applicants assert that the written description provided in the Specification would convey to those of ordinary skill in the art that the invention includes the genus and that Applicant was in possession of the claimed genus. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph is respectfully requested.

35 U.S.C. § 112, first paragraph Rejection – Enablement

The Examiner has also rejected Claims 11-13 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. Specifically, the Examiner states that Claims 11-13 "contain subject matter which was not described in the Specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention." In order to expedite prosecution, and not to concede to the Examiner's rejection, Applicants have canceled Claims 11-13 and reserve the right to pursue the subject matter of these claims in a divisional and/or continuation application.

CONCLUSION

In view of the foregoing amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the finality of the action be removed and that the application be passed to issue. If the Examiner feels that a telephone call would expedite the prosecution of this case, the Examiner is invited to call the undersigned at (781) 398-2548.

Respectfully submitted,

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